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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/642,851 | 08/18/2003 | Anne M. Pianca | AB-334U | 4016 |
| 23845 | 7590 | 06/06/2005 | EXAMINER | |
| ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355 | | | ALTER, ALYSSA M | |
| | | | ART UNIT. | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,851

Applicant(s)

PIANCA ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/06/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "wherein the paddle electrode connector" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner recommends changing the "system of claim 8", to -- the system of claim 10 --.

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 6, line 2, "its" is vague. The examiner is unsure if it is referring to the cannula or the lumen.

b. Claims 1 and 6, "a reference platform" is inferentially included. It is unclear if the Applicant is functionally reciting the platform or positively reciting the platform. The examiner is interpreting the claim as containing the platform. However, the platform should first be cited in the claim before it is used.

c. Claims 2 and 7, "a stereotactic frame" is inferentially included and is unclear if the Applicant is functionally reciting the stereotactic frame or positively reciting the stereotactic frame. The examiner is interpreting the claim as containing the

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stereotactic frame. However, the stereotactic frame should first be cited in the claim before it is used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hogg et al. (US 6,527,782). Hogg et al. discloses a guide for controlling the orientation of a medical device. The guide includes a cannula with a sheath disposed within the cannula's inner lumen. The sheath also has a lumen for the delivery of a medical device. The examiner considers the claimed cannula slit along its length to be the sheath/guide. It is noted that the claim does not state that the cannula slit extends along its "entire" length. Therefore since the medical device is placed within the sheath, which is located within the cannula's lumen, the medical device is inherently placed within the cannula's lumen.

"The guide 20 can be used to deploy any type of medical device in the body, including catheters and cannulas, endoscopes, laser devices, RF devices, cryo devices, drug needles, biopsy tools, physiological sensors, deep brain stimulators, or other

diagnostic and therapeutic devices”(col. 5, lines 11-16). Therefore since the medical device can be a cannula or catheter, both of which have a lumen, the deployed medical device inherently has an inner lumen.

Figures 23 and 24 displays a lock mechanism that “can be provided to secure the guide member 464 in a selected position”(col. 9, lines 58-60). The lock secures the guide member, which the examiner considers to be the claimed reference platform.

“The guide 300 further comprises a plate 310, intermediate the proximal and distal ends by which the guide can be secured to the skull of a patient”(col. 7, lines 31-35).

According to Merriam-Webster {see Reference V}, stereotactic or stereotaxic means “of, relating to, or being a technique or apparatus used in neurological research or surgery for directing the tip of a delicate instrument (as a needle or an electrode) in three planes in attempting to reach a specific locus in the brain.” Therefore, the examiner considers the guide 300 to be part of a stereotactic frame as seen in figure 15, since it is used to direct a medical device into the brain. In addition, since the guide member, which is considered to be the reference platform, is connected to the plate by means of the cannula, the examiner considers the reference platform to be connected to the stereotactic frame.

Also, 464 in figures 23-24 can be used to lock the medical device at an offset, as seen in figure 24. According to Merriam-Webster {see Reference U}, offset can mean “an abrupt change in the dimension of profile of an object or the part set off by such change.” Therefore, the medical device inherently has an offset portion that can be

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secured by a lock mechanism, since figure 24 displays the off-set portion of the medical device.

As to claim 16, the guide further comprises an electrode of a deep brain stimulator, as seen in figure 15 and 16. Since Hogg et al. has an electrode, there is inherently an electrode connector within the lead.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 5-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogg et al. (US 6,527,782) in view of Zonenshayn (US 6,301,492). Hogg et al. discloses the claimed invention except for the microelectrode in the lead lumen. Zonenshayn teaches that it is known to utilize a microelectrode recording (MER) lead mounted within a deep brain stimulation lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the medical device as taught by Hogg et al. with the microelectrode in the lead lumen as taught by Zonenshayn, in order to combine single-cell recording and deep brain stimulation to minimize complications by improving accuracy in placement.

As to claims 5 and 12, Hogg et al. discloses the claimed invention except for the discontinuing the lumen of the lead into the offset portion. Zonenshayn teaches that it is

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known to have a closed active distal tip of a deep stimulation lead as set forth in column 3, lines 60-63. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the open deep brain stimulation lead as taught by Hogg et al. with the closed end lead as taught by Zonenshayn, in order to utilize a stylet to stiffen and guide the deep brain stimulation lead. Since it would have been obvious to create a lead with a closed distal end, the lead would therefore not have a lumen continue through to the offset portion.

2. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Hogg et al. (US 6,527,782), as applied to claims 5-9 and 12 above, in further view of Chinn et al. (US Patent Publication 20020143376). The modified Hogg et al. discloses the claimed invention except for the paddle electrode connector and connection to a cable and external trial stimulator. Chinn et al. teaches that it is known to utilize a paddle lead connected to a cable of an external trial stimulator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode connector as taught by the modified Hogg et al. with the paddle lead connected to a cable of an external trial stimulator as taught by Chinn et al. since such a modification would allow the paddle lead to stimulate a larger surface area and a external trial stimulator reduces the risk of infection while determining if electrical stimulation is a viable option of treatment for the patient.

3. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogg et al. (US 6,527,782) in view of Heruth et al. (US 5,713,858). Hogg et al. discloses the claimed invention except for the means of securing the lock to the lead. Heruth et al.

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teaches that it is known to use a lock with a spring-loaded latch to clamp the outer surface of the lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the lock mechanism as taught by Hogg et al. with the lock as taught by Heruth et al., in order to directly secure the lead itself, instead of the lead orientation, to ensure that the lead would not extend farther than required for treatment.

The modified Hogg et al. discloses the claimed invention but does not disclose expressly securing the lock to the lead through pinching, suturing or piercing means. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify securing the lock to the lead through clamping as taught by the modified Hogg et al., with the pinching, suturing or piercing means, because Applicant has not disclosed the other securing means provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with securing the lock to the lead through clamping as taught by the modified Hogg et al., because both means lock the lead in position to prevent unwanted movement of the lead.

Therefore, it would have been an obvious matter of design choice to modify the securing means of the lock to the lead to obtain the invention as specified in the claim(s).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GEORGE R. EVANISKO
PRIMARY EXAMINER

5/27/5


Alyssa M Alter
Examiner
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AAA